Application No.: 10/026937

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [ ] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: The Sequence in Fig. 2A needs a SEQ ID NO. The number can be included in the description of the drawings.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,937	12/21/2001	Keith D. Allen	R-632 CIP	7301

7590 07/16/2003

DELTAGEN, INC.
740 Bay Road
Redwood City, CA 94063

EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,937	ALLEN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL.** 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

Claims 1-40 are pending and under consideration.

The computer readable format of the sequence listing filed had errors, but was entered by STIC. The disk had non-ASCII "garbage" at the beginning/end of files that were deleted by STIC.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequence in Fig. 2A is not described in the sequence listing originally filed. A new CRF and paper listing is required with the new sequence. The number should be incorporated into the description of the sequence on pg 10, line 27.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a construct having a first and second polynucleotide sequence homologous to an FPR-RS4 gene and a selectable marker, classified in class 435, subclass 320.1.

II. Claims 3-9, 14-22 and 34-37 drawn to a cell having a disruption in an FPR-RS4 gene, classified in class 435, subclass 325, and transgenic animals having a disruption in an FPR-RS4 gene, classified in class 800, subclass 8,

III. Claims 10, 23, 29-32 and 38, drawn to a method of identifying a compound using a transgenic animal having a disruption in an FPR-RS4 gene, classified in class 800, subclass 3.

IV. Claims 11 and 12, drawn to a method identifying a compound using a cell having a disruption in an FPR-RS4 gene, classified in various classes and subclasses.

V. Claims 13, 24 and 25, drawn to agonists of FPR-RS4, classified in various classes and subclasses.

VI. Claims 13, 24 and 25, drawn to antagonists of FPR-RS4, classified in various classes and subclasses.

VII. Claim 26, drawn to phenotypic data, having an unknown class and subclass.

VIII. Claims 27, 28 and 39, drawn to methods of treatment using FPR-RS4 protein, classified in class 530, subclass 350.

IX. Claim 33, drawn to testing using cells expressing FPR-RS4, classified in 435, subclass 325

X. Claim 40, drawn to FPR-RS4 protein, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together. The targeting construct does not have a disruption in the FPR-RS4 gene while the cells and animals of Invention II require a disruption in the FPR-RS4 gene.

Inventions I and III or IV are patentably distinct because the construct can be used to encode FPR-RS4 while the claims of Invention III or IV must have a disruption in the FPR-RS4 gene. DNA encoding FPR-RS4 has a different structure and function than cells or transgenics having DNA with a disruption in the FPR-RS4 gene. The burden required to search DNA encoding FPR-RS4 and disrupting an FPR-RS4 gene together would be undue.

Inventions I and V or VI are unrelated. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for agonists

or antagonists of an FPR-RS4. The agonists or antagonists of an FPR-RS4 do not require the targeting construct and vice versa.

Inventions I and VII are unrelated. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for data. The data does not require the targeting construct and vice versa.

Inventions I and VIII are patentably distinct because the construct encodes FPR-RS4 while the method treats disease. The protocols and reagent for constructs and for treating disease using protein are materially distinct and separate. The construct does not require the method and the method does not require the construct.

Inventions I and IX are patentably distinct because the construct can be used to disrupt the FPR-RS4 protein while the method of Group IX requires cells transfected with a vector encoding FPR-RS4. The protocols and reagents required to make and use a construct having a disruption in FPR-RS4 are materially distinct and separate from those required to for a cell transfected with DNA encoding FPR-RS4. The construct does not require the method and the method does not require the construct.

Inventions I and X are patentably distinct because the construct can be used to disrupt FPR-RS4 genes while the protein can be used to isolate antibodies. The protocols and reagent for constructs and protein are materially distinct and separate. The construct does not require the protein and the protein does not require the construct.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be performed using cells or transgenics. The burden required to search an in vitro method with an in vivo method would be undue.

Inventions II and IV are related as product and process of use. In the instant case the method can be performed using cells or transgenics. The burden required to search an in vitro method with an in vivo method would be undue.

Inventions II and V or VI are patentably distinct because, for example, transgenics are used as in vivo models while the agents are used to treat disease. The protocols and reagents required for cells or transgenics having a disruption of an FPR-RS4 gene are materially distinct and separate from those required for agonists or antagonists of an FPR-RS4. The cells/transgenics do not require the agonists or antagonists and vice versa.

Inventions II and VII are patentably distinct because, for example, transgenics are used as in vivo models while the data is used for calculations. The protocols and reagents required for cells and transgenics are materially distinct and separate from those required for data. Nor is "data" associated with a transgenic mouse having a disruption of an FPR-RS4 gene specific to such a mouse. Therefore, the data does not require the cells or transgenics and vice versa.

Inventions II and VIII are patentably distinct because the cells or transgenics can be used to test compounds while the method treats disease. The protocols and reagent

for cells and transgenics and for treating disease using protein are materially distinct and separate. The cells or transgenics do not require administering FPR-RS4 and the method does not require the cells or transgenics.

Inventions II and IX are patentably distinct because the cells/transgenics have a disruption of the FPR-RS4 gene while the method of Group IX requires cells transfected with a vector encoding FPR-RS4. The protocols and reagents required to make and use a cells/transgenics having a disruption in FPR-RS4 are materially distinct and separate from those required to make/use a cell transfected with DNA encoding FPR-RS4. The cells/transgenics do not require the method and the method does not require the cells/transgenics.

Inventions II and X are patentably distinct because the cells or transgenics can be used to test compounds while the protein can be used to isolate antibodies. The protocols and reagent for cells/transgenics having a disruption in an FPR-RS4 gene are materially distinct and separate from the FPR-RS4 protein. The cells/transgenics do not require the protein and the protein does not require the cells/transgenics.

Inventions III and IV are patentably distinct because the method of Group III requires a transgenic while the method of Group IV requires cells. The protocols and reagents required for testing compounds *in vivo* are materially distinct and separate than those required to test compounds *in vitro*. The method of Group III does not require the method of Group IV and vice versa. The burden required to search an in vitro method with an in vivo method would be undue.

Inventions III and V or VI are patentably distinct because the method is used to identify compounds while the agents are used to treat disease. The protocols and reagents required for using transgenics having a disruption of an FPR-RS4 gene are materially distinct and separate from those required for agonists or antagonists of FPR-RS4. The method does not require the agonists or antagonists and vice versa.

Inventions III and VII are patentably distinct because the method is used to identify compounds while the data is used for calculations. The protocols and reagents required for using transgenics to identify compounds are materially distinct and separate from data. Nor is "data" associated with a transgenic mouse having a disruption of an FPR-RS4 gene specific to such a mouse. Therefore, the data does not require the method of using transgenics as it can be found elsewhere, and the method does not require the data.

Inventions III and VIII are patentably distinct because the method of using transgenics can be used to test compounds while the method of administering FPR-RS4 treats disease. The protocols and reagent for using transgenics to identify compounds and for treating disease using FPR-RS4 protein are materially distinct and separate. The method of identifying compounds does not require FPR-RS4 or administering FPR-RS4. The method of administering FPR-RS4 does not require using transgenics.

Inventions III and IX are patentably distinct because the method of Group III requires the transgenics have a disruption of the FPR-RS4 gene while the method of Group IX requires the cells express FPR-RS4. The protocols and reagents required to

disrupt FPR-RS4 are materially distinct and separate from those required for expressing FPR-RS4. The method of Group III does not require the method of Group IX and vice versa.

Inventions III and X are patentably distinct because the method of using transgenics can be used to identify compounds while the protein can be used to isolate antibodies. The protocols and reagent for using transgenics having a disruption in an FPR-RS4 gene are materially distinct and separate from the FPR-RS4 protein. The method of identifying compounds using transgenics does not require the protein and the protein does not require the method.

Inventions IV and V or VI are patentably distinct because the method is used to identify compounds while the agents are used to treat disease. The protocols and reagents required for using cells having a disruption of an FPR-RS4 gene are materially distinct and separate from those required for agonists or antagonists of FPR-RS4. The method does not require the agonists or antagonists and vice versa.

Inventions IV and VII are patentably distinct because the method is used to identify compounds while the data is used for calculations. The protocols and reagents required for using cells to identify compounds are materially distinct and separate from data. Nor is "data" associated with a cell having a disruption of an FPR-RS4 gene. The data does not require the method of using cells, and the method does not require the data.

Inventions IV and VIII are patentably distinct because the method of using cells can be used to test compounds while the method of administering FPR-RS4 treats

disease. The protocols and reagent for using cells to identify compounds and for treating disease using FPR-RS4 protein are materially distinct and separate. The method of identifying compounds does not require FPR-RS4 or administering FPR-RS4. The method of administering FPR-RS4 does not require using cells.

Inventions IV and IX are patentably distinct because the method of Group IV requires the cells have a disruption of the FPR-RS4 gene while the method of Group IX requires the cells express FPR-RS4. The protocols and reagents required to disrupt FPR-RS4 are materially distinct and separate from those required for expressing FPR-RS4. The method of Group IV does not require the method of Group IX and vice versa.

Inventions IV and X are patentably distinct because the method of using cells can be used to identify compounds while the protein can be used to isolate antibodies. The protocols and reagent for using cells having a disruption in an FPR-RS4 gene are materially distinct and separate from the FPR-RS4 protein. The method of identifying compounds using cells does not require the protein and the protein does not require the method.

Inventions V and VI are patentably distinct because the agonist is used to increase the function of FPR-RS4 2 while the antagonist is used to decrease the function of FPR-RS4. The agonist and antagonist have different structures and would require different searches. The agonist does not require the antagonist and vice versa.

Inventions V and VII are patentably distinct because the agonist is used to increase the function of FPR-RS4 2 while the data is used for calculations. The

protocols and reagents required for agonists are materially distinct and separate from data. The agonist does not require data and data does not require the agonist.

Inventions V and VIII are patentably distinct because the agonist is used to increase the function of FPR-RS4 2 while the method of administering FPR-RS4 treats disease. The protocols and reagent for agonists are materially distinct and separate than those required for treating disease using FPR-RS4 protein. The agonist does not require FPR-RS4 or administering FPR-RS4. The method of administering FPR-RS4 does not require the agonist.

Inventions V and IX are patentably distinct because the agonist is used to modulate FPR-RS4 expression or function while the method of Group IX is used to identify such agents. The protocols and reagents required for agents are materially distinct and separate from those required for making/using cells transfected with DNA encoding FPR-RS4. The agonist does not require the method of Group IX and method does not require the agonist.

Inventions V and X are patentably distinct because the agonist is used to increase the function of FPR-RS4 2 while the protein can be used to isolate antibodies. The protocols and reagent for agonists and proteins are materially distinct and separate. The agonist does not require the protein and the protein does not require the agonist.

Inventions VI and VII are patentably distinct because the antagonist is used to decrease the function of FPR-RS4 2 while the data is used for calculations. The protocols and reagents required for antagonists are materially distinct and separate

from data. The antagonist does not require data and data does not require the antagonist.

Inventions VI and VIII are patentably distinct because the agonist is used to decrease the function of FPR-RS4 2 while the method of administering FPR-RS4 treats disease. The protocols and reagent for antagonists are materially distinct and separate than those required for treating disease using FPR-RS4 protein. The antagonist does not require FPR-RS4 or administering FPR-RS4. The method of administering FPR-RS4 does not require the antagonist.

Inventions VI and IX are patentably distinct because the antagonist is used to modulate FPR-RS4 expression or function while the method of Group IX is used to identify such agents. The protocols and reagents required for agents are materially distinct and separate from those required for making/using cells transfected with DNA encoding FPR-RS4. The antagonist does not require the method of Group IX and method does not require the antagonist.

Inventions VI and X are patentably distinct because the antagonist is used to decrease the function of FPR-RS4 2 while the protein can be used to isolate antibodies. The protocols and reagent for antagonists and proteins are materially distinct and separate. The antagonist does not require the protein and the protein does not require the antagonist.

Inventions VII and VIII are patentably distinct because the data is used for calculations while the method of administering FPR-RS4 treats disease. The protocols and reagent for data are materially distinct and separate than those required for treating

disease using FPR-RS4 protein. The data does not require FPR-RS4 or administering FPR-RS4. The method of administering FPR-RS4 does not require the data.

Inventions VII and IX are patentably distinct because the data is used for calculations while the method of Group IX is used to identify such agents. The protocols and reagents required for data are materially distinct and separate from those required for making/using cells transfected with DNA encoding FPR-RS4. The data does not require the method of Group IX and method does not require the data.

Inventions VII and X are patentably distinct because the data is used for calculations while the protein can be used to isolate antibodies. The protocols and reagent for data and proteins are materially distinct and separate. The data does not require the protein and the protein does not require the data.

Inventions VIII and IX are patentably distinct because the method of Group VIII is used to treat disease while the method of Group IX is used to identify agents that modulate FPR-RS4 expression/function. The protocols and reagents required for treating disease are materially distinct and separate from those required for identifying agents using cells transfected with DNA encoding FPR-RS4. The method of treatment does not require the method of identifying agents using transfected cells and the method of identifying agents does not require the method of treatment.

Inventions VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the process can be performed with a different product and the product can be used in a different process. Specifically, method of treatment can be with a compound identified in the method of Groups V or VI instead of using FPR-RS4 protein. And the protein does not have to be used for treatment and can be used to isolate antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I-X is separate, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

MICHAEL WILSON
PRIMARY EXAMINER